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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/643,982	Applicant(s) ST. VILLE, JAMES A.	
	Examiner Kandasamy Thangavelu	Art Unit 2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-26,29-42,45 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-26,29-42,45 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Introduction

1. This communication is in response to the Applicants' Amendments dated October 8, 2004. Claims 1-3, 12-20, 25, 29-37 and 39-41 were amended. Claims 10-11, 27-28, 43-44 and 46-55 were cancelled. Claim56 was added. Claims 1-9, 12-26, 29-42, 45 and 56 of the application are pending in the application. This office action is made non-final in response to the applicant's Request for Continued Examination.

Drawings

2. The drawings are objected to; see a copy of Form PTO-948 sent with paper No. 12 for an explanation.

Claim Objections

3. The following is a quotation of 37 C.F.R § 1.75 (d)(1):

> The claim or claims must conform to the invention as set forth in the remainder of the specification and terms and phrases in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.

4. Claims 1-9, 12-26, 29-42, 45 and 56 are objected to because of the following informalities:

Claim 1, Line 2, refers to field { f } while line 7 refers to force { f }. This is inconsistent use of the same symbol f to refer to two different items.

Claim 25, Line 3, refers to field { f } while line 7 refers to force { f }. This is inconsistent use of the same symbol f to refer to two different items.

Claim 41, Line 2, refers to field { f } while line 8 refers to force { f }. This is inconsistent use of the same symbol f to refer to two different items.

Claims objected to but not specifically addressed are objected to based on their dependency to an objected claim.

Appropriate corrections are required.

Claim Interpretations

5. In Claim 1, Line 7 force { f } has been interpreted as field { f }.

In Claim 25, Line 7 force { f } has been interpreted as field { f }.

In Claim 41, Line 8 force { f } has been interpreted as field { f }.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 4-9, 13, 19, 21-26, 30, 36 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667) and **Phipps et al.** (U.S. Patent 6,289,242).

8.1 **St. Ville** teaches a method and apparatus for manufacturing a prosthesis having optimized response characteristics. Specifically, as per Claim 1, **St. Ville** teaches a method for manufacturing an object having a potential { x } that is generated in response to a field { f } applied (Col 4, Lines 43-45 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49); and

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

calculating a material property matrix [k] based on the force { f } and potential { x } (Col 4, Lines 51-52);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing equipment control parameters for each volume increment of the object based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38; Col 13, Line 1-8; Lines 21-23); and

controlling the manufacturing equipment in accordance with the determined manufacturing equipment control parameters to thereby manufacture the object (Col 4, Lines 61-62; Col 12, Lines 13-18; Col 14, Lines 44-48);

wherein, if the material property coefficients correspond to a composite material, the manufacturing equipment control parameters comprises parameters for controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 12, Lines 39-42; Col 14, Lines 51-55);

and controlling of the manufacturing equipment comprises controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 14, Lines 51-58).

St. Ville does not expressly teach that the composite material comprises structural fibers laminated in a matrix. **Castanie et al.** teaches the composite material comprises structural fibers laminated in a matrix (Col 1, Lines 9-11; Col 1, Lines 14-21; Col 2, Line 67 to Col 3, Line 3), because this facilitates producing an article having high strength, accuracy and temperature

resistance characteristics (Col 1, Lines 11-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville I** with method of **Castanie et al.** that included the composite material comprising structural fibers laminated in a matrix. The artisan would have been motivated because that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

St. Ville teaches determining variables for the respective volume increments of the object (Col 13, Lines 1-8 and 21-23). **St. Ville** does not expressly teach a matrix into which an impurity is introduced, the amount of impurity introduced into the matrix being controllably variable for the respective volume increments of the object. **Yamazaki** teaches a layer or region into which an impurity is introduced, the amount of impurity introduced into the layer or region being controllably variable for the respective volume increments of the object (Col 1, Lines 65-67; Col 2, Lines 44-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Yamazaki** that included a layer or region into which an impurity is introduced, the amount of impurity introduced into the layer or region being controllably variable for the respective volume increments of the object. The artisan would have been motivated because introducing impurity into the object would provide a technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

St. Ville does not expressly teach a matrix into which an impurity is introduced. **Johnson et al.** teaches a matrix into which an impurity is introduced (Col 2, Lines 36-42; Col 2,

Lines 55-56; Col 2, Lines 34-37; Col 1, Lines 27-32; Col 6, Lines 13-25; Col 6, Lines 61-65), because as per **Phipps et al.** that allows introducing a variety of agents into the host by combining with the matrix (Col 16, Lines 46-48). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Yamazaki** and **Johnson et al.** that included a matrix into which an impurity is introduced. The artisan would have been motivated because that would allow introducing a variety of agents into the composite material host by combining with the matrix.

8.2 As per Claim 4, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** also teaches generating of a computerized mathematical model of the object includes determining the smallest volume increment that can be manufactured using the manufacturing equipment. (Col 13, Lines 1-8 and Col 13, Lines 21-23).

8.3 As per Claim 5, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** also teaches that the field { f } is a mechanical force field and the potential { x } is a displacement. (Col 7, Lines 53-67).

8.4 As per Claim 6, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** also teaches that the field {f} is an electric current field and the potential { x } is a voltage. (Col 7, Lines 53-67).

8.5 As per Claim 7, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** also teaches that the field {f} is a magnetic field and the potential { x } is a magnetic vector potential. (Col 7, Lines 53-67).

8.6 As per Claim 8, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** also teaches that the field {f} is a thermal flux field and the potential { x } is a temperature. (Col 7, Lines 53-67).

8.7 As per Claim 9, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** also teaches that the field { f } is a fluid velocity field and the potential {x} is a fluid potential. (Col 7, Lines 53-67).

8.8 As per Claim 13, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises bone. **Johnson et al.** teaches that the impurity comprises bone (Col 6, Lines 13-25), since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30) It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Johnson et al.** that specified that the impurity comprised bone. The artisan would have been motivated because that would provide an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair.

8.9 As per Claim 19, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises antibiotics. **Phipps et al.** teaches that the impurity comprises antibiotics (Col 16, Lines 46-50), since antibiotics could be introduced into the host for use as anti-infectives (Col 16, Lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Phipps et al.** that specified that the impurity comprised antibiotics. The artisan would have been motivated because antibiotics could be introduced into the host for use as anti-infectives.

8.10 As per Claim 21, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

8.11 As per Claim 22, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** teaches an object made in accordance with the method of claim 1 (Col 6, Lines 58-62);

the object is selected from the group consisting of an automobile part, an aircraft part, a prosthetic implant, a golf club shaft, a tennis racket, a bicycle frame, and a fishing pole (Col 6, Lines 58-62); and

different portions of the object have different material properties corresponding to the matched extracted material property coefficients for known materials (Col 4, Lines 46-59).

8.12 As per Claim 23, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** teaches a prosthetic implant manufactured in accordance with the method of claim 1 (Col 8, Lines 23-35 and Col 8, Lines 39-44).

8.13 As per Claim 24, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** teaches a golf club manufactured in accordance with the method of claim 1. (Col 6, Lines 58-62).

8.14 As per Claim 25, **St. Ville** teaches a computer-implemented method for determining machine control instructions for manufacturing an object having a potential { x } that is generated in response to a field {f} applied (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49); and

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

calculating a material property matrix [k] based on the force { f } and potential { x } (Col 4, Lines 51-52);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing equipment control parameters for each volume increment of the object based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38; Col 13, Line 1-8; Lines 21-23); and

generating machine control instructions for controlling the manufacturing equipment in accordance with the manufacturing equipment control parameters to y manufacture the object (Col 14, Lines 49-53);

wherein, if the material property coefficients correspond to a composite material, the manufacturing equipment control parameters comprises parameters for controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 12, Lines 39-42; Col 14, Lines 51-55);

and machine control instructions comprise instructions for controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 14, Lines 44-48; Col 14, Lines 51-58).

St. Ville does not expressly teach that the composite material comprises structural fibers laminated in a matrix. **Castanie et al.** teaches the composite material comprises structural fibers laminated in a matrix (Col 1, Lines 9-11; Col 1, Lines 14-21; Col 2, Line 67 to Col 3, Line 3), because this facilitates producing an article having high strength, accuracy and temperature resistance characteristics (Col 1, Lines 11-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Castanie et al.** that included the composite material comprising structural fibers laminated in a matrix. The artisan would have been motivated because that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

St. Ville teaches determining variables for the respective volume increments of' the object (Col 13, Lines 1-8 and 21-23). **St. Ville** does not expressly teach a matrix into which an impurity is introduced, the amount of impurity introduced into the matrix being controllably variable for the respective volume increments of the object. **Yamazaki** teaches a layer or region into which an impurity is introduced, the amount of impurity introduced into the layer or region being controllably variable for the respective volume increments of the object (Col 1, Lines 65-67; Col 2, Lines 44-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Yamazaki** that included a layer or region into which an impurity is introduced, the amount of impurity introduced into the layer or region being controllably variable for the respective volume increments of the object. The artisan would have been motivated

because introducing impurity into the object would provide a technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

St. Ville does not expressly teach a matrix into which an impurity is introduced. **Johnson et al.** teaches a matrix into which an impurity is introduced (Col 2, Lines 36-42; Col 2, Lines 55-56; Col 2, Lines 34-37; Col 1, Lines 27-32; Col 6, Lines 13-25; Col 6, Lines 61-65), because as per **Phipps et al.** that allows introducing a variety of agents into the host by combining with the matrix (Col 16, Lines 46-48). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Yamazaki** and **Johnson et al.** that included a matrix into which an impurity is introduced. The artisan would have been motivated because that would allow introducing a variety of agents into the composite material host by combining with the matrix.

8.15 As per Claim 26, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 25. **St. Ville** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

8.16 As per Claim 30 it is rejected based on the same reasoning as Claim 13, supra. Claim 30 is a method claim reciting the same limitation as Claim 13, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.**

8.17 As per Claim 36, it is rejected based on the same reasoning as Claim 19, supra. Claim 36 is a method claim reciting the same limitation as Claim 19, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.**

8.18 As per Claim 38, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 25. **St. Ville** also teaches a computer system programmed to perform the method of claim 25 (Col 13, Line 53 to Col 14, Line 58 and Col 14, Lines 59-61).

8.19 As per Claim 39, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 25. **St. Ville** also teaches a control system programmed with machine control instructions for controlling composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Col 12, Lines 23-25 and Col 12, Lines 39-42).

8.20 As per Claim 40, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 25. **St. Ville** also teaches composite manufacturing equipment comprising a control system programmed with machine control instructions for controlling the composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Fig. 10; Col 12, Lines 39-42 and Col 15, Lines 28-42).

8.21 As per Claim 41, **St. Ville** teaches a method for manufacturing an object for which a defined field { f } generates a potential {x} in response (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49);

specifying values of the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

calculating a material property matrix [k] based on the force { f } and potential { x } (Col 4, Lines 51-52);

wherein the material property matrix [k] comprises a plurality of values each corresponding to one or more material property coefficients (Col 4, Lines 53-59);

comparing each of the plurality of values in the material property matrix [k] to known material properties (Col 4, Lines 55-59);

responsive to a match, selecting a corresponding manufacturing process parameter for a volume increment of the object, wherein the selected manufacturing process parameter is usable for controlling composite manufacturing equipment if the matched known material property is a material property for a composite material (Col 4, Lines 59-61 and Col 12, Lines 23-25; Col 13, Line 1-8; Lines 21-23); and

controlling the composite manufacturing equipment in accordance with the selected manufacturing process parameters to thereby manufacture the object (Col 14, Lines 44-48).

St. Ville does not expressly teach that the composite material comprises structural fibers laminated in a matrix. **Castanie et al.** teaches the composite material comprises structural fibers laminated in a matrix (Col 1, Lines 9-11; Col 1, Lines 14-21; Col 2, Line 67 to Col 3, Line 3), because this facilitates producing an article having high strength, accuracy and temperature resistance characteristics (Col 1, Lines 11-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Castanie et al.** that included the composite material comprising structural fibers laminated in a matrix. The artisan would have been motivated because that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

St. Ville teaches determining variables for the respective volume increments of' the object (Col 13, Lines 1-8 and 21-23). **St. Ville** does not expressly teach a matrix into which an impurity is introduced, the amount of impurity introduced into the matrix being controllably variable for the respective volume increments of the object. **Yamazaki** teaches a layer or region into which an impurity is introduced, the amount of impurity introduced into the layer or region being controllably variable for the respective volume increments of the object (Col 1, Lines 65-67; Col 2, Lines 44-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Yamazaki** that included a layer or region into which an impurity is introduced, the amount of impurity introduced into the layer or region being controllably variable for the respective volume increments of the object. The artisan would have been motivated

because introducing impurity into the object would provide a technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

St. Ville does not expressly teach a matrix into which an impurity is introduced. **Johnson et al.** teaches a matrix into which an impurity is introduced (Col 2, Lines 36-42; Col 2, Lines 55-56; Col 2, Lines 34-37; Col 1, Lines 27-32; Col 6, Lines 13-25; Col 6, Lines 61-65), because as per **Phipps et al.** that allows introducing a variety of agents into the host by combining with the matrix (Col 16, Lines 46-48). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Yamazaki** and **Johnson et al.** that included a matrix into which an impurity is introduced. The artisan would have been motivated because that would allow introducing a variety of agents into the composite material host by combining with the matrix

8.22 As per Claim 42, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 41. **St. Ville** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

9. Claims 56 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of

Yamazaki (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242) and **Wu et al.** (U.S. Patent 5,654,077).

9.1 As per claim 56, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** teaches that the method includes specifying the material properties of the finite elements (Col 4, Lines 51-52). **St. Ville** does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **Wu et al.** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as both **St. Ville** and **Wu et al.** deal with material properties of multimaterial laminate, and the symmetry eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Wu et al.** specifying that the material properties of the finite elements have a particular symmetry. The artisan would have been motivated because both **St. Ville** and **Wu et al.** deal with material properties of multimaterial laminate, and the symmetry would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

9.2 As per Claim 2, **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Wu et al.** teach the method of Claim 56. **St. Ville** does not expressly teach that the material properties of the finite elements are specified to be isotropic. **Wu et al.** teaches that the material

properties of the finite elements are specified to be isotropic (Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Wu et al.** that included the material properties of the finite elements being specified to be isotropic. The artisan would have been motivated because that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242), **Wu et al.** (U.S. Patent 5,654,077) and **Legere** (U.S. Patent 6,087,571).

10.1 As per Claim 3, **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Wu et al.** teach the method of Claim 56. **St. Ville** does not expressly teach that the material properties of the finite elements are specified to be transversely isotropic. **Legere** teaches that the material properties of the finite elements are specified to be transversely isotropic (Col 6, Lines 55-65), so the material will have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction (Col 6, Lines 53-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Legere** that specifies

that the material properties of the finite elements be transversely isotropic. The artisan would have been motivated because then the material would have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction.

11. Claims 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242), and **Abatangelo et al.** (WO 97/18842).

11.1 As per Claim 12, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises biologic material. **Abatangelo et al.** teaches that the impurity comprises biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue (Page 2, Para 4). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Abatangelo et al.** that specifies that the impurity comprising biologic material. The artisan would have been motivated because it would be possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue.

11.2 As per Claim 29, it is rejected based on the same reasoning as Claim 12, supra. Claim 29 is a method claim reciting the same limitation as Claim 12, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Abatangelo et al.**

12. Claims 14 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242), and **Bonadio et al.** (U.S. Patent 5,942,496).

12.1 As per Claim 14, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises crushed bone. **Bonadio et al.** teaches that the impurity comprises crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Bonadio et al.** that specified that the impurity comprised crushed bone. The artisan would have been motivated because this material would have the ability to simulate new bone formation.

12.2 As per Claim 31, it is rejected based on the same reasoning as Claim 14, supra. Claim 31 is a method claim reciting the same limitation as Claim 14, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Bonadio et al.**

13. Claims 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242) and **Warren, Jr.** (U.S. Patent 6,348,042).

13.1 As per Claim 15, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises co-factors. **Warren, Jr.** teaches that the impurity comprises co-factors (abstract; Col 2, Lines 38-52), as the cofactors activate the enzyme impregnated in the lumen, within the biological system (Col 3, Lines 10-12). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Warren, Jr.** that specified that the impurity comprised co-factors. The artisan would have been motivated because the cofactors activate the enzyme impregnated in the lumen, within the biological system.

13.2 As per Claim 32, it is rejected based on the same reasoning as Claim 15, supra. Claim 32 is a method claim reciting the same limitation as Claim 15, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Warren, Jr.**

14. Claims 16 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in

view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242) and **Tadros et al.** (U.S. Patent 6,121,033).

14.1 As per Claim 16, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises biological cells. **Tadros et al.** teaches that the impurity comprises biological cells (Col 14, Lines 39-52), as biological cells are completely degradable into biomass without having toxic effect on the microbes (Col 14, Lines 41-43). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Tadros et al.** that specified that the impurity comprised biological cells. The artisan would have been motivated because biological cells are completely degradable into biomass without having toxic effect on the microbes.

14.2 As per Claim 33, it is rejected based on the same reasoning as Claim 16, supra. Claim 33 is a method claim reciting the same limitation as Claim 16, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Tadros et al.**

15. Claims 17 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242) and **Slaikeu** (U.S. Patent 6,231,590).

15.1 As per Claim 17, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises bio-active materials. **Slaikeu** teaches that the impurity comprises bio-active materials (Col 7, Lines 15-21), since such materials have properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis, coagulation or platelet activity (Col 7, Lines 8-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Slaikeu** that specified that the impurity comprised bio-active materials. The artisan would have been motivated because that would allow manufacturing including bio-active materials which would be useful to reducing friction, providing a therapeutic for local or blood delivery etc.

15.2 As per Claim 34, it is rejected based on the same reasoning as Claim 17, supra. Claim 34 is a method claim reciting the same limitation as Claim 17, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Slaikeu.**

16. Claims 18 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242) and **Hermann** (U.S. Patent 5,098,621).

16.1 As per Claim 18, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises

medications. **Hermann** teaches that the impurity comprises medications (Col 9, Lines 49-55), as medications could be dispensed for the dressings (Col 9, Lines 51-52). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Hermann** that specified that the impurity comprised medications. The artisan would have been motivated because that would allow medications to be dispensed for the dressings.

16.2 As per Claim 35, it is rejected based on the same reasoning as Claim 18, supra. Claim 35 is a method claim reciting the same limitation as Claim 18, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Hermann.**

17. Claims 20 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667), **Phipps et al.** (U.S. Patent 6,289,242) and **Mavity et al.** (U.S. Patent 6,248,057).

17.1 As per Claim 20, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises radioactive materials. **Mavity et al.** teaches that the impurity comprises radioactive materials (Col 2, Lines 1-5), since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer (Abstract). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of

Mavity et al. that specified that the impurity comprised radioactive materials. The artisan would have been motivated because they would be useful for a variety of medical purposes, being particularly suitable for treatment of cancer.

17.2 As per Claim 37, it is rejected based on the same reasoning as Claim 20, supra. Claim 37 is a method claim reciting the same limitation as Claim 20, as taught throughout by **St. Ville, Castanie et al., Yamazaki, Johnson et al., Phipps et al.** and **Mavity et al.**

18. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), **Yamazaki** (U.S. Patent 6,197,624), **Johnson et al.** (U.S. Patent 6,296,667) and **Phipps et al.** (U.S. Patent 6,289,242), and further in view of **Wu et al.** (U.S. Patent 5,654,077), **Abatangelo et al.** (WO 97/18842), **Bonadio et al.** (U.S. Patent 5,942,496), **Warren, Jr.** (U.S. Patent 6,348,042), **Tadros et al.** (U.S. Patent 6,121,033), **Slaikeu** (U.S. Patent 6,231,590), **Hermann** (U.S. Patent 5,098,621) and **Mavity et al.** (U.S. Patent 6,248,057).

18.1 As per Claim 45, **St. Ville, Castanie et al., Yamazaki, Johnson et al.** and **Phipps et al.** teach the method of Claim 41. **St. Ville** does not expressly teach that the impurity is selected from the group consisting of: biologic materials, bone, crushed bone, co-factors, biological cells, bio-active material, medications, antibiotics, and radioactive materials.

Abatangelo et al. teaches that the impurity is selected from biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue (Page 2, Para 4). **Johnson et al.** teaches that the impurity is selected from bone (Col 6, Lines 13-25), since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30). **Bonadio et al.** teaches that the impurity is selected from crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36). **Warren, Jr.** teaches that the impurity is selected from co-factors (abstract; Col 2, Lines 38-52), as the cofactors activate the enzyme impregnated in the lumen, within the biological system (Col 3, Lines 10-12). **Tadros et al.** teaches that the impurity is selected from biological cells (Col 14, Lines 39-52), as biological cells are completely degradable into biomass without having toxic effect on the microbes (Col 14, Lines 41-43). **Slaikeu** teaches that the impurity is selected from bio-active materials (Col 7, Lines 15-21), since such materials have properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis, coagulation or platelet activity (Col 7, Lines 8-11). **Hermann** teaches that the impurity is selected from medications (Col 9, Lines 49-55), as medications could be dispensed for the dressings (Col 9, Lines 51-52). **Phipps et al.** teaches that the impurity is selected from antibiotics (Col 16, Lines 46-50), since antibiotics could be introduced into the host for use as anti-infectives (Col 16, Lines 46-50). **Mavity et al.** teaches that the impurity is selected from radioactive materials (Col 2, Lines 1-5), since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with

- the method of **Abatangelo et al.** that specified that the impurity was selected from biologic material, since it would be possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue;

- method of **Johnson et al.** that specified that the impurity was selected from bone, since that would provide an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair;

- method of **Bonadio et al.** that specified that the impurity was selected from crushed bone, since this material has the ability to simulate new bone formation;

- method of **Warren, Jr.** that specified that the impurity was selected from co-factors, as the cofactors activate the enzyme impregnated in the lumen, within the biological system;

- method of **Tadros et al.** that specified that the impurity was selected from biological cells, as biological cells are completely degradable into biomass without having toxic effect on the microbes;

- method of **Slaikeu** that specified that the impurity was selected from bio-active materials, since that would describe the manufacturing method for materials including bio-active materials which would be useful to reducing friction, providing a therapeutic for local or blood delivery etc;

- method of **Hermann** that specified that the impurity was selected from medications, since medications could be dispensed for the dressings;

- method of **Phipps et al.** that specified that the impurity was selected from antibiotics, since antibiotics could be introduced into the host for use as anti-infectives; and

- method of **Mavity et al.** that specified that the impurity was selected from radioactive materials, since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer.

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville,** so the impurity is selected from the group consisting of: biologic materials, bone, crushed bone, co-factors, biological cells, bio-active material, medications, antibiotics, and radioactive materials, to achieve the desired benefits.

Response to Arguments

19. Applicant's arguments filed on October 8, 2004 have been fully considered. The arguments with respect to 103 (a) rejections of Claims 1, 25 and 41 are moot in view of the new ground(s) of rejection which are applied against the amended claims. The applicant's amendments necessitated the new grounds of rejection.

19.1 As per the applicant's argument that "Claims 1, 25 and 41 have been amended to describe methods in which the structural fibers of a composite material are laminated in a matrix into which an impurity is introduced, the amount of impurity introduced into the matrix being controllably variable for the respective volume increments of the object; the proposed combination of St. Ville, Wu et al. and Yamazaki does not teach or suggest introducing an

impurity into the matrix of the composite material as claimed; ..the crystalline silicon layer into which Yamazaki introduces impurities is not the matrix of a composite material; ... Castanie et al. contains no disclosures of introducing impurities into the matrix of a composite material; ... Legere et al. does not disclose introducing an impurity into the matrix of a composite material; none of the other references teaches or suggests introducing an impurity into the matrix of a composite material", the examiner has used **Castanie et al., Yamazaki** and **Johnson et al.**

Castanie et al. teaches the composite material comprises structural fibers laminated in a matrix (Col 1, Lines 9-11; Col 1, Lines 14-21; Col 2, Line 67 to Col 3, Line 3), because this facilitates producing an article having high strength, accuracy and temperature resistance characteristics (Col 1, Lines 11-13).

Yamazaki teaches a layer or region into which an impurity is introduced, the amount of impurity introduced into the layer or region being controllably variable for the respective volume increments of the object (Col 1, Lines 65-67; Col 2, Lines 44-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40).

Johnson et al. teaches a matrix into which an impurity is introduced (Col 2, Lines 36-42; Col 2, Lines 55-56; Col 2, Lines 34-37; Col 1, Lines 27-32; Col 6, Lines 13-25; Col 6, Lines 61-65), because that allows introducing a variety of agents into the host by combining with the matrix (**Phipps et al.:** Col 16, Lines 46-48).

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on 571-272-3716. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 2123
November 20, 2004

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